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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,238	09/17/2003	Eric Kolb	DEP-5156	3713
27777	7590	09/22/2005	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			REIP, DAVID OWEN	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/664,238	Applicant(s) KOLB ET AL.	
	Examiner David O. Reip	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/22/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the first and second bore axes intersecting at a point on a side of the plate *proximal* to the first and second vertebrae (ref. claim 14) and the first and second bore axes being parallel to one another and oriented at an angle other than perpendicular to a longitudinal axis of the plate (ref. claim 17) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The examiner finds no issues under 112 1st and 2nd paragraphs, and notes with appreciation the careful drafting of claims by the applicant's representative, including ensuring consistency of claim limitations and proper antecedents throughout the various chains of dependent claims. This cooperative effort helps speed prosecution and contributes greatly to the applicant receiving, if ultimately granted, the highest quality patent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-8, 11-13, 15, 16, 19, 22, 23, 26, and 35-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Jackowski et al (WO 00/22999). (Note: since this reference is in French, the applicant will find it helpful to refer to the corresponding English language U.S. Pat. 6,565,571.) Figs. 1-5 of Jackowski show a spinal fixation plate having all the limitations as recited in the above listed claims, including: first and

second sections, each canted downward from a horizontal longitudinal axis at approximately 15 degrees; a first and a second bores 19 and 20 with axes that 1) are each oriented at an angle other than perpendicular to a longitudinal axis of their respective sections, 2) intersect at a point on a side of the plate distal to the vertebrae, and 3) are angled at approximately 72 degrees from the horizontal longitudinal axis; and an "opening" 29 to permit graft visualization.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al (U.S. Pat. 6,454,769) in view of Brace et al (U.S. Pat. 6,235,033), Jackowski et al (U.S. 6,565,571), Sevrain (U.S. Pat. Pub. 2003/0229348), and LeHuec et al (U.S. Pat. 6,793,658). Wagner shows a spinal fixation plate having all the limitations as recited in the claims, except for: canted ends; bores angled such that their axes intersect proximal to the vertebrae; a dynamic configuration comprising a slot and pin; the polyaxial bushings having a plurality of ridges on an outer surface, and; a fin. Brace teaches polyaxial bushings having ridges (see Fig. 5) -- it would have been obvious to the skilled artisan to add ridges to the Wagner bushings to enhance the locking effect upon expansion. Jackowski teaches a plate having canted ends and outwardly angled bores-- it would have been obvious to the skilled artisan to cant the ends of the Wagner plate from 0-20 degrees to more closely match the contour of the plate to the contour of the vertebral section upon which it is being applied. Note that canting a bone plate to conform to a natural bone surface is an old and well-known practice -- see Getscher et al (U.S. Pat. 3,824,995), Mears (U.S. Pat. 4,454,876), David et al (U.S. Pat. 4,800,874), and Vichard (U.S. Pat. 5,318,567). Note also that canting the ends of the Wagner plate would also "automatically" tilt the screw bore axes inward such that their axes would intersect at a point proximal to the vertebrae. It would have also been obvious to the skilled artisan to outwardly angle the bores in the four corners of the Wagner plate to "automatically" guide the screws toward a more stable, center of mass position in each vertebral body. Sevrain teaches a dynamic plate construction comprising a slot and pin (see Figs. 7-10) -- it would have been obvious to the skilled

Art Unit: 3731

artisan to create a modified embodiment of the Wagner plate in a two-piece, dynamic configuration as taught by Sevrain, especially when using the Wagner plate in combination with a bone graft, to (paraphrasing the express motivation from the second column on page 4 of Sevrain) substantially eliminate stresses that are present in a static plate/screws system caused by the gradual relative displacement between the vertebrae that takes place when an intradiscal bone graft contracts as it fuses into the vertebrae. Lastly, LeHuec teaches a spinal plate with a fin 24 (see Figs. 2, 3b and 3c) -- it would have been obvious to the skilled artisan to modify Wagner to include a similar fin to enhance stability and positioning of the plate in the desired location.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David O. Reip whose telephone number is 571-272-4702. The examiner can normally be reached on 7 A.M.- 4:30 P.M. Mon-Thu and every other Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4917. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "David O. Reip". The signature is fluid and cursive, with a large, stylized "D" and "R".

David O. Reip
Primary Examiner
AU 3731